

MPG-8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Sandra Wegert
Group : 1647
Applicants : Pardo-Fernandez et al.
Application No. : 09/694,777
Confirmation No.: 8515
Filed : October 23, 2000
For : NOVEL HUMAN K⁺ ION CHANNEL AND THERAPEUTIC
APPLICATIONS THEREOF

New York, New York
November 30, 2001

Hon. Commissioner for Patents
Washington, D.C. 20231

Response to Office Action

This is in response to the August 30, 2001 Office Action in the above-identified application. Applicants have filed concurrently herewith a Petition for a two-month extension of time for replying to the Office Action and have paid the fee required under 37 C.F.R. §§ 1.136(a) and 1.17(a)(2). With the extension, the time for response is extended up to and including November 30, 2001.

The Restriction Requirement

The Examiner states that claims 1-33 stand subject to restriction under 35 U.S. C. § 121. Specifically, the Examiner states that there are 11 groups of inventions:

- I. Claims 1-10, 14, 15 and 32, drawn to nucleic acids, compositions comprising nucleic acids, complementary nucleic acids, vectors, host cells and methods of producing polypeptides recombinantly;
- II. Claim 8, drawn to a multicellular organism transformed with a recombinant vector;
- III. Claims 11, 15, 32 and 33, drawn to a polypeptide K⁺ channel and compositions comprising;
- IV. Claims 12, 13, 15 and 32, drawn to antibodies against a polypeptide;
- V. Claims 16-18, 20, 21, 25, 30 and 31, drawn to a method of gene therapy;
- VI. Claims 19-21 and 30, drawn to a method of modulating the activity of a polypeptide using an antibody;
- VII. Claims 19-21, drawn to a method of modulating the activity of a polypeptide using an H₁ antagonist;
- VIII. Claims 22 and 24, drawn to methods of molecular modeling;
- IX. Claims 23 and 24, drawn to a method of identifying inhibitors of nucleic acid expression;
- X. Claims 26-30, drawn to a method of detecting a polypeptide;
- XI. Claims 26, 29 and 30, drawn to a method of detecting a polynucleotide.

The Examiner further states that the applicant is required to select one sequence from the following two groups:

- (a) SEQ ID NO: 3 or 4
- (b) SEQ ID NO: 13 or 14.

The Examiner contends that the inventions of Groups I-IV are independent and distinct, each from the other, because they are products that possess characteristic differences in structure and function and each with an independent utility that is distinct for each invention and cannot be exchanged. Applicants traverse the restriction of the claims of Groups I and II.

The Examiner specifically states that the nucleic acid of Groups I and II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The Examiner states that the sequences of Groups (a)-(b) above represent patentably distinct inventions because they have different putative functions, different structures, and require different search terms, starting points and strategies. The Examiner concludes that restriction is proper because the proteins and nucleic acids of Groups (a) and (b) require a completely separate search.

First, applicants seek to correct the Examiner's mis-statements regarding the claims of Groups I and II. The

Examiner states that Group I is "drawn to nucleic acids, compositions comprising nucleic acids, complementary nucleic acids, vectors, host cells, and methods of producing polypeptides recombinantly...." The Examiner has neglected to recite that the claims of Group I include, *inter alia*, compositions comprising a polypeptide and antibodies directed against these polypeptides, and kits comprising a nucleic acid molecule, vectors comprising the nucleic acid, polypeptides and/or antibodies directed against these polypeptides (see, for example, claims 14, 15 or 32).

The Examiner refers to "[t]he nucleic acids of Groups I and II...." However, applicants note that the claims of Group II are not drawn to nucleic acids but rather a host transformed with nucleic acid molecules of Group I.

The Examiner states that Group II is "drawn to a multicellular organism transformed with a recombinant vector,..." However, applicants note that the host in Group II comprises both single cells and multicellular organisms.

Second, the Examiner has not provided a specific reason for the restriction of Groups I and II. In fact, the Examiner has included claim 8 in Groups I and II. Applicants believe the restriction may have been unintentional. In case it was not, applicants do not believe the restriction is proper.

The Manual of Patent Examining Procedure (MPEP) states that there are two criteria for a proper requirement of restriction between patentably distinct inventions. The first is that the inventions must be independent or distinct as claimed. The second is that there must be a serious search and examination burden on the Examiner if restriction is not required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP § 803.

Claim 8 is directed to a host transformed with a vector comprising a nucleic acid sequence encoding a K⁺ channel protein of Group I or that specifically hybridizes to the nucleic acid molecule of claim 1. Applicants agree that the host can be a single cell or multicellular organism. Regardless of whether the host cell of claim 8 is single cell or a multicell, applicants believe there is no undue burden on the Examiner to search the multicellular organisms of claim 8 with all the organisms of claim 8 (Group I).

Conclusion

Applicants request that the Examiner reconsider the restriction of the claims of Groups I and II. If the Examiner

agrees with the proposal, applicants provisionally elect the new grouping for initial substantive examination. If the Examiner does not agree with this proposal, pursuant to 37 C.F. R. § 1.143, applicants provisionally elect the claims of Group I. As requested by the Examiner, applicants select SEQ ID NO: 14. This election is made expressly without waiver of applicants' rights to continue to prosecute and to obtain claims to the non-elected subject matter either in this application or in another application benefit herefrom.

Respectfully submitted,



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